

ICS 11.040.40



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Non-active surgical implants - Osteosynthesis and joint
replacement implants - Part 1: Particular requirements for
osteosynthesis implants**

(English Translation)

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1 Scope

This document specifies particular requirements for non-active surgical implants for osteosynthesis (hereinafter referred to as the "implants").

This document provides particular requirements regarding intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information supplied by the manufacturer.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

YY/T 0640-2016 Non-active surgical implants - General requirements (ISO 14630.2012, IDT)

3 Terms and Definitions

The terms and definitions defined in YY/T 0640-2016, as well as the following terms and definitions, are applicable to this document.

3.1 Non-Active Surgical Implants for Osteosynthesis

Non-active surgical implants intended to provide support for bone, cartilage, tendon, or ligament structures.

4.1 General

The intended performance shall comply with the requirements of Clause 4 of YY/T 0640-2016, while also taking into account the requirements of 4.2 to 4.4.

NOTE: Due to the diversity of anatomical sites, fracture locations, and applications, osteosynthesis

5 Design Attributes

Clause 5 of YY/T 0640-2016 and the following particular requirements apply.

a) When an implant is part of a connection system, its shape, dimensions, and tolerances shall be such that its intended use and function are not impaired.

NOTE 1: When an implant consists of two or more components, the design must take into account potential wear as well as electrolytic and corrosive effects [compare with Items 5 a), c), h), k), and l) of YY/T 0640-2016].

b) Where applicable, the dimensions of the implant shall be consistent with the anatomical characteristics of the human body into which it is to be implanted.

NOTE 2: The design of the implants must take into account factors such as anatomical structure, the type of tissue defect, bone rehabilitation, and fusion rates; the final design may represent a compromise to satisfy these varying requirements.

c) To minimize use errors, implant designers consider the required operative techniques as well as appropriate maintenance and handling of the implant, provided that these do not interfere with the implant's intended use and function.

NOTE 3: Appendix B provides an informative list of common implant designs; these specific applications have been proven acceptable in practice.

6 Materials

Clause 6 of YY/T 0640-2016 applies.

NOTE: Standards concerning materials for implants, the suitability of which has been demonstrated through clinical use, are provided in Appendix C.

7.1 General

For preclinical evaluation, the implant shall be evaluated in accordance with Clause 7 of YY/T

0640-2016 and the following particular requirements.

NOTE: Appendix D lists standards that can be used to assess whether different types of implants meet the aforementioned requirements.

7.2 Preclinical Evaluation

The requirements in 7.2 of YY/T 0640-2016 apply, together with the following particular requirements.

a) In vitro simulated-use testing shall be conducted to verify the intended interactions between the implant and surgical instruments, and, where applicable, the intended interactions between interconnected implants. Where applicable, if the removal of the implant cannot be evaluated through direct comparison with existing instruments, cadaveric evaluation should be performed if possible.

b) When evaluating implants using static and/or dynamic load testing, recognized test standards (where applicable) or test models customized to the implant's characteristics shall be used. Due to the diversity of implants and their characteristics, test standards may not exist or may require modification as needed.

c) Biological, physical, or modeling studies may be used to demonstrate that the implant achieves its intended performance, provided that they are appropriately verified.

NOTE 1: Existing data on similar implants or design characteristics are taken into account during preclinical evaluation.

NOTE 2: Test methods may involve different levels of testing.

a) Basic technical tests characterizing the implant or implant components (e.g., tension, bending, torsion);

b) Tests under expected loading conditions for installed components;

c) Biomechanical performance tests of assembled components (bone may be replaced by suitable artificial materials);

d) Static or dynamic tests (cyclic fatigue).

NOTE 3: Specific implants may be tested under specific loading and/or environmental conditions to evaluate their performance.

7.3 Clinical Evaluation

Section 7.3 of YY/T 0640-2016 applies.

7.4 Post-Market Follow-Up

Section 7.4 of YY/T 0640-2016 applies.

8 Manufacturing

Clause 8 of YY/T 0640-2016 applies.

9 Sterilization

Clause 9 of YY/T 0640-2016 applies.

10 Packaging

Clause 10 of YY/T 0640-2016 applies.

11.1 General

Section 11.1 of YY/T 0640-2016 applies.

11.2 Label

Section 11.2 of YY/T 0640-2016 applies.

11.3 Instructions for Use

The requirements in 11.3 of YY/T 0640-2016 apply, together with the following particular requirements. The information supplied by the manufacturer shall include the following data under the corresponding conditions.

- a) Restrictions on any modifications to the implant after delivery, e.g., dimensions, shape, surface condition.
- b) Date of issue or latest revision of the instructions for use.

11.4 Restrictions on Combinations

Section 11.4 of YY/T 0640-2016 applies.

11.5 Implant Marking

The requirements in 11.5 of YY/T 0640-2016 apply, together with the following particular requirements.